

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

MY HEALTH, INC.,

Plaintiff,

Case No. 2:14-cv-683-JRG-RSP

v.

LIFESCAN, INC.,

Defendant.

**MY HEALTH, INC.'S RESPONSE TO
DEFENDANT LIFESCAN, INC.'S MOTION TO DISMISS PURSUANT TO
FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)**

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I. INTRODUCTION

My Health, Inc. filed this suit against Lifescan, Inc. (“*LifeScan*”) for infringement of U.S. Patent No. 6,612,985 (the “*’985 patent*”). LifeScan responded with a 12(b)(6) Motion to Dismiss (“*Motion*”), arguing that the claims of the ’985 patent are directed to abstract ideas and mental processes, and are therefore invalid under 35 U.S.C. § 101 for failing to claim patentable subject matter.

The Court should deny LifeScan’s Motion because (1) deciding subject matter eligibility before claim construction is premature, and (2) the ’985 claims are directed to patentable subject matter.

II. STATEMENT OF ISSUES

1. Whether it is premature in this case to make a 35 U.S.C. § 101 ruling before claim construction which could affect the issue of patentable subject matter, where this suit represents a normal patent case, as opposed to a “rare” or “exceptional” circumstance that would allow an early ruling.

2. Whether, if the Court determines that claim construction is not necessary to address § 101, the claims at issue are directed to patentable subject matter.

III. BACKGROUND

The ’985 patent was filed on February 26, 2001 and after a two-and-a-half (2½) year review by the USPTO it issued on September 2, 2003. Exhibit A to the Complaint (’985 patent). The named inventors, Dr. Michael Eiffert and Dr. Lisa Schwartz, developed the claimed technology while working as scientists and researchers of the University of Rochester, the original assignee. Compl. ¶¶ 3-8. Drs. Eiffert and Schwartz are pioneers in mobile medicine,

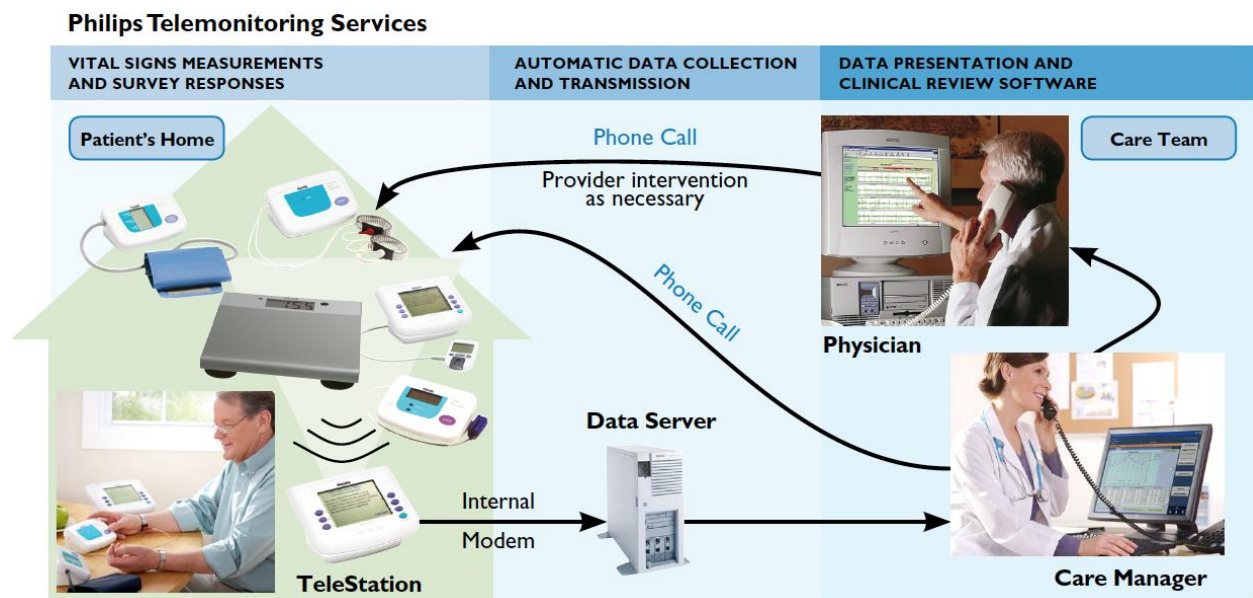
disclosing in the '985 patent unique technology that assists healthcare providers in monitoring and treating patients from a remote location. *Id.* Dr. Eiffert is the CEO of My Health and is internationally recognized for his advances in healthcare communication. *Id.*

The '985 patent has been licensed by industry leaders including Philips [Case No. 2:2013-cv-00140-JRG-RSP], Honeywell [Case No. 2:2013-cv-00139-JRG-RSP], Medtronic/Cardiacom [Case No. 2:2013-cv-00136-JRG-RSP], and Zeomega [Case No. 2:2012-cv-00251-JRG-RSP], among others. Each of these companies entered into a license based on their extensive review of the patent.¹

IV. ARGUMENT

A 12(b)(6) motion to dismiss is granted only if a complaint does not “contain a ‘short and plain statement of the claim showing that the pleader is entitled to relief.’” *Rockstar Consortium US LP, Inc. v. Samsung Elecs. Co., Ltd.*, No. 2:13-cv-00900-JRG at *6 (E.D. Tex. May 15, 2014)

¹ By way of example, see the accused product Philips Remote Patient Monitoring System [Case No. 2:2013-cv-00140, Complaint (Dkt. 1)]:



(citing Fed. R. Civ. P. 8(a)). Because an issued patent is presumed valid, invalidity for lack of subject matter eligibility “must be proven by clear and convincing evidence.” *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1304-05 (Fed. Cir. 2013 *aff’d* *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014)). LifeScan’s Motion should be denied because My Health has met its pleading requirements, and LifeScan cannot meet its burden of proving by clear and convincing evidence that the ’985 patent claims ineligible subject matter under §101.

More specifically, the Court should deny LifeScan’s Motion for two independent reasons. First, deciding subject matter eligibility before claim construction is premature because this is a normal case where eligibility depends on the meaning of terms whose constructions merit factual and legal development. The patent provides for remote health care administration through a novel means of gathering data remotely and updating a treatment plan in connection with a current assessment, treatment guidelines, and compliance data as these terms are understood in the context of the patent. For example, the scope of claim construction of key terms could affect the issue of whether the alleged abstract claims pre-empt an entire field. Second, if the Court finds that this is a “rare” or “exceptional” case where subject matter eligibility should be decided now, the Motion should be denied because the ’985 patent claims are directed to patentable subject matter.

A. LifeScan’s Motion is Premature Because this is Not a “Rare” or “Exceptional” Case Where Subject Matter Eligibility Should be Decided before Claim Construction.

“[I]t will ordinarily be desirable — and often necessary — to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter.” *Bancorp Servs. v. Sun Life Assurance Co.*, 687 F.3d 1266, 1273-74 (Fed. Cir. 2012); *Omega Eng’g., Inc v. Raytek Corp.*,

334 F. 3d 1314, 1335 (Fed. Cir. 2003) (“The first step in any invalidity analysis is claim construction.”). This Court recently confirmed, as it has on multiple previous occasions, the strong interest in completing claim construction before determining subject matter eligibility. *Rockstar Consortium US LP, Inc.*, No. 2:13-cv-00900-JRG at *6 at *6-7 (explaining that “[i]f there are factual disputes about the patent’s claims . . . the question of patentable subject matter should be reserved until claim construction”); *Macrosolve, Inc. v. Geico Ins. Agen., Inc.*, No. 6:12-cv-74-MHS-JDL (E.D. Tex. Feb. 5, 2013) (finding that “[h]ere, where the claims of unpatentability relate directly to the scope and meaning of a claim term, it is not only prudent, but necessary for the Court to conduct claim construction prior to determining the patentability of the subject matter under 35 U.S.C § 101.”); *Dietgoal Innovations LLC v. Tyson Foods, Inc.*, No. 2:12-cv-338-JRG-RSP at *2 (E.D. Tex. Mar. 25, 2013) (citing *In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008), *aff’d*, 130 S. Ct. 3218 (2010) (“The Federal Circuit has held that claim construction is an important first step in any § 101 analysis. The Court agrees that claim construction briefing, along with supporting evidence, may be necessary to determine whether the patent-in-suit contains patent-eligible subject matter.”).

The strong interest in construing claims before determining patent eligibility results because “the analysis under § 101 . . . is rife with underlying factual issues [and] . . . requires a search for limitations in the claims that narrow or tie the claims to specific applications of an otherwise abstract concept.” *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1338-39 (Fed. Cir. 2013), *cert. granted, vacated and remanded sub nom. WildTangent, Inc. v. Ultramercial, LLC*, No. 13-255, 2014 U.S. LEXIS 4647 (June 30, 2014).² Although claim construction is a question

² LifeScan states that *Ultramercial* “is no longer good law.” Motion at 18. *Ultramercial*’s reasoning is cited in this Court’s decision in *Rockstar Consortium US LP, Inc. v. Samsung Elecs. Co., Ltd*, No. 2:13-cv-00900-JRG at *6 (E.D. Tex. May 15, 2014). *Ultramercial* was vacated

of law, it is informed by numerous factual questions tied up in intrinsic and extrinsic evidence. This intrinsic and extrinsic evidence includes, *e.g.*, the claims, the specification, the prosecution history, related patents and their prosecution histories, dictionaries, treatises, evidence of the characteristics of a person having ordinary skill in the art, and evidence as to how a person of ordinary skill in the art would have understood particular claim terms. *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Co.*, No., 2012-1014 (Fed. Cir. 2014); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-24 (Fed. Cir. 2005). None of these legal and factual issues have been developed in a 12(b)(6) motion to dismiss, which has been filed in the earliest stages of litigation.

LifeScan's cited authority illustrates only that where special or uncommon circumstances exist, it may be appropriate to decide subject matter eligibility before claim construction. For example, *Lumen View* explained that its pre-claim-construction finding under § 101 was a "rare" exception. "[I]t will be rare that a patent infringement suit can be dismissed at the pleading stage for lack of patentable subject matter because every issued patent is presumed to have been issued properly, absent clear and convincing evidence to the contrary." *Lumen View Tech. LLC v. Findthebest.com, Inc.*, 984 F. Supp. 2d 189, 204 (S.D.N.Y. Nov. 22, 2013) (quoting *Ultramercial*, 722 F.3d at 1338). The Southern District of New York in *Lumen View* ultimately ruled on the patentable subject matter issue before claim construction because in that case, unlike

after the issuance of the *Alice* decision for further review in light of that ruling. However, there is no reason to conclude that the lower court's prior decision is spurious, or that the reasoning in *Rockstar* is now irrelevant. Rather, it is likely that the finding in *Ultramercial* will not change since it relies on the reasoning in the Supreme Court's *Bilski* decision that is cited extensively, and approvingly in *Alice*. *Bilski v. Kappos*, 130 Sup.Ct. 1328 (2010). The Supreme Court concludes that *Alice* itself "follows from . . . *Bilski* in particular." *Alice*, 134 S. Ct. at 2356. The rationale in *Ultramercial* follows from *Bilski*, and is mirrored in *Alice*. LifeScan is unable to articulate why the *Ultramercial* analysis is irrelevant, or why this Court's ruling in *Rockstar* is inapplicable here (addressed more below).

in the present case, the claims had “[n]o components [that were] opaque such that claim construction would be necessary to flush out [their] contours” and “construction was not necessary to reveal any material legal issues....” *Lumen View*, 984 F. Supp. 2d at 205. In that “rare” circumstance subject matter eligibility was “not a close question.” *Id.* Conversely, as discussed below, there are multiple limitations of the ’985 claims that could affect the § 101 analysis.

Clear with Computers and *Uniloc* also presented unusual circumstances. In *Clear with Computers*, the Court addressed ineligibility on a 12(c) motion for judgment on the pleadings (as opposed to a 12(b)(6) motion), but only after the parties in that case had filed a Joint Claim Construction and Prehearing Statement including disputed terms, the parties’ proposed constructions, and intrinsic and extrinsic evidence supporting proposed constructions. *Clear With Computers, LLC v. Dick’s Sporting Goods, Inc.*, No. 6:12-cv-674 at *6 (E.D. Tex. Jan. 21, 2014) (citing Joint Claim Construction and Prehearing Statement, Dkt. No. 102 (Nov. 22, 2013)).

In *Uniloc*, the court found invalidity for lack of subject matter eligibility where there were no claim construction disputes, and the plaintiff did not point to any specific claim construction uncertainties that would preclude a determination of subject matter eligibility. *Uniloc USA, Inc. v. Rackspace Hosting, Inc.*, No. 6:12-cv-375 (E.D. Tex. Mar. 27, 2013); *Uniloc*, No. 6:12-cv-375, Pl.’s Opp.to Mot. to Dismiss, Dkt. No. 23 at *1-2 (Sept. 13, 2012).

In *Bancorp*, LifeScan’s lead authority, the court found subject matter ineligibility on a motion for summary judgment. The record was well developed, and the parties had already “submitted two rounds of briefing on claim construction issues.” *Bancorp Servs. v. Sun Life Assurance Co.*, 771 F. Supp. 2d 1054, 1058 (2011). Clearly, this is not the case here, where the only operative pleading is the Complaint and an Answer has yet to be filed.

LifeScan's application of *Bilski* is only marginally relevant to the timing of considering a § 101 motion because the parties in *Bilski* did not appeal any claim construction disputes. *In re Bilski*, 545 F.3d at 951 (“Although claim construction . . . is an important first step in a § 101 analysis . . . there is no claim construction dispute in this appeal.”). The Supreme Court in its ruling did not address the claim construction issue because it was not appealed, but despite not being appealed, the Federal Circuit went out of its way to note that determining subject matter eligibility before claim construction was an exception to the norm. *Id.* (citing *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368, 1370 (Fed. Cir. 1998)).

In contrast to the facts in LifeScan's cited authority, the '985 patent does not present a “rare” exception, but rather is an ordinary situation in which it is “desirable” and “necessary” to “resolve claim construction disputes prior to a § 101 analysis” because “the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter.” *Bancorp*, 687 F.3d at 1273-74. Unlike the court in *Bancorp*, this Court has not benefitted from two rounds of claim construction briefing. Unlike *Lumen View*, the subject matter eligibility question of the '985 patent is not such an obvious case where “construction [i]s not necessary to reveal any material legal issues....” Unlike *Clear with Computers*, which raised the issue in a 12(c) motion on the pleadings after the parties had undertaken construction analysis, LifeScan raises subject matter eligibility in a 12(b)(6) motion to dismiss when the only substantive entry on the docket is the Complaint. And finally, unlike *Uniloc*, multiple terms in the claims of the '985 patent merit construction.

By way of a brief example (discussed more below), claim construction proceedings might develop arguments and evidence for the term “providing the patient with the reviewed treatment plan,” relating to how and what information is conveyed through equipment and peripherals, the

type of review, and the nature of the treatment plan. Separately, construction of the term “treatment plan” could be helpful to the Court and the parties in differentiating between what LifeScan contends is any run-of-the-mill medical plan, and what the patent discloses as a type of treatment plan based on particular categories of data gathered at a remote location through certain processes and apparatuses.

Additionally, the term “compliance data” may be developed through claim construction proceedings in a manner that identifies the nature of devices necessary to “generate and provide” compliance data where the patient and provider are at remote locations. The definition of other claim terms including “current assessment” and “treatment guidelines,” will implicate whether an abstract category of conduct is pre-empted by the invention, or whether the invention is a tangible improvement in mobile medicine which was the foundation of Drs. Eiffert’s and Schwartz’s research.

Resolving these anticipated disputes requires an analysis of the ’985 patent specification, the prosecution history, and related patents, reviewing appropriate dictionaries and treatises, and potentially considering evidence from retained technical experts regarding the characteristics of how a person of ordinary skill in the art would understand the claim terms. Factual and legal development is appropriate to determine whether LifeScan’s broad-sweeping conclusion that the ’985 patent “pre-empts use” of an “an abstract idea for treating and monitoring a remote patient, nothing more” is meritorious.

B. If LifeScan’s Motion is Not Denied as Premature, the ’985 Patent Claims Survive Because LifeScan Cannot Establish by Clear and Convincing Evidence that the Patent is Not Directed to Patentable Subject Matter.

If the Court determines that it is not premature to decide LifeScan’s challenge to subject matter eligibility at this stage, the Motion should be denied because the ’985 patent claims are

directed to patentable subject matter. The patent provides for remote health care administration through a novel means of gathering data remotely and updating a treatment plan in connection with a current assessment, treatment guidelines, and compliance data as these terms are understood in the context of the patent. Further, the '985 patent claims are not abstract because they are limited to a "new and useful" application of computing and networking equipment to improve remote health care monitoring. Each of these reasons justifies denial of the Motion.

The court need not engage in an analysis as to whether claims are novel, or non-obvious, since these issues are not before the court on a challenge to subject matter eligibility.

1. 35 U.S.C. § 101 and Recent Case Law Interpretation.

Section 101 of the Patent Act defines the four broad categories of patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. "In choosing such expansive terms ... modified by the comprehensive word 'any.' Congress plainly contemplated that the patent laws would be given a wide scope." *Bilski v. Kappos*, 130 S. Ct. 1328, 1332 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). However, to avoid permitting an overly broad grant of rights that could "pre-empt use of [an] approach in all fields and [] effectively grant a monopoly over an abstract idea," "[l]aws of nature, natural phenomena, and abstract ideas" are non-patentable exceptions to § 101. *Alice Corp. Pty. Ltd.*, 134 S. Ct. at 2354 (2014). The Supreme Court has acknowledged that the analysis is inherently flawed, because "[a]t some level, 'all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'" *Id.* at 2354 (quoting *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012)) Yet, they are not patent-ineligible "simply because [an invention] involves an abstract concept." *Id.* at 2354 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)).

The repeated concern with granting a patent on an abstract idea is that an entire field will be pre-empted. *Alice Corp. Pty. Ltd.*, 134 S. Ct. at 2354; *Accenture Global Services, GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336 (Fed. Cir. 2013). Logically then, if a patent does not pre-empt an entire field, it should not be considered an unpatentable abstract idea. *See id.* This rule of thumb makes sense in light of the Supreme Court’s acknowledgment that at some level all inventions could be characterized as an abstract idea, and the difficulty of characterizing an idea as “abstract” or otherwise. *Alice*, 134 S.Ct. at 1293; *Accenture*, 728 F.3d at 1347 (Rader, C.J., dissenting (“[A]ny claim can be stripped down, simplified, generalized, or paraphrased to remove all of its concrete limitations, until at its core, something that could be characterized as an abstract idea is revealed. A court cannot go hunting for abstractions by ignoring the concrete, palpable, tangible limitations of the invention the patentee actually claims.”)).

[P]rior to granting *en banc* review in [*Alice v.*] *CLS Bank*, this court commented: ‘no one understands what makes an idea abstract.’ After *CLS Bank*, nothing has changed. ‘Our opinions spend page after page revisiting our cases and those of the Supreme Court, and still we continue to disagree vigorously over what is or is not patentable subject matter.’ Indeed, deciding what makes an idea ‘abstract’ is ‘reminiscent of the oenologists trying to describe a new wine.’

Id (citations omitted). Chief Judge Rader concluded by taking the “opportunity to reiterate [his] view that ‘the remedy is the same: consult the statute’!” *Accenture*, 728 F.3d at 1348, (Rader, C.J. dissenting). The statute offers broad categories of patent-eligible subject matter: “any new and useful process, machine, [or] manufacture ...” The “ineligible” subject matter in these system claims is a further testament to the perversity of a standard without rules—the result of abandoning the statute.” *Id.*

In *Alice* and *Mayo* the Supreme Court described a two-step analysis to “distinguish[] ... abstract ideas from patent-eligible applications of those concepts.” *Alice*, 134 S. Ct. at 2355 (citing *Mayo Collaborative Servs.*, 132 S. Ct. at 1294). The first step is to determine whether a

claim is directed to an abstract idea. *Id.* (citing *Mayo*, 132 S. Ct. at 1296-97). In the second step, a court “search[es] for an ‘inventive concept,’” asking, “[w]hat else is there in the claims before us [other than the abstract idea]?” *Id.* (quoting *Mayo*, 132 S. Ct. at 1294, 1297). “Applications of such concepts to a new and useful end . . . [are] eligible for patent protection.” *Id.* at 2354 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

Regarding the second step, applications of abstract concepts to a new and useful end may include the integration of computer or processing equipment as a patentable improvement: “To salvage an otherwise patent-ineligible process, a computer must be integral to the claimed invention, facilitating the process in a way that a person making calculations or computations could not.” *Bancorp*, 687 F.3d at 1278 (citing *SiRF Tech., Inc. v. Int’l Trade Comm’n*, 601 F.3d 1319, 1333 (Fed. Cir. 2010)). In an earlier articulation of the same principle, the Federal Circuit explained, “[i]n order for the addition of a machine to impose a meaningful limit on the scope of a claim, it must play a significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly, *i.e.*, through the utilization of a computer for performing calculations.” *SiRF*, 601 F.3d at 1333. Although a trivial computer implementation will not transform an otherwise abstract idea, an application of computer technology to a “new and useful” end, where the computer limitation is integral to the claimed invention, is sufficient to ensure that the idea is non-abstract.

2. *The ’985 patent Claims Are Not Directed to an Abstract Idea, Therefore LifeScan’s Analysis under 35 U.S.C. § 101 is Inapplicable and the Motion Should be Denied.*

A primary matter in assessing patent eligibility is to determine whether a patent is directed to a law of nature, a natural phenomenon, or an abstract idea. If it is not, and it meets the minimum inventive threshold of “any new and useful process, machine, manufacture, or

composition of matter,” then § 101 has been satisfied and the inquiry ends. If, on the other hand, it appears that the patent is directed to an impermissible category, then a determination is made as to whether the application of the invention is sufficiently concrete to avoid invalidation.

LifeScan does not allege that the '985 patent is directed to a law of nature or a natural phenomenon. Instead, it alleges that the patent covers an abstract idea. An analysis of the claims of the '985 patent under *Mayo/Alice* and related governing case law demonstrates that it is in fact not directed to an abstract concept, but rather a tangible invention. Consequently, LifeScan's § 101 analysis does not apply to this patent, and the Motion should be denied on this separate ground.

In *Alice*, the Supreme Court commenced its analysis by considering whether the patent-at-issue was directed towards an abstract idea. The patent was a disfavored business method, which covered the broad concept of “intermediated settlement.” *Alice*, 134 S.Ct. at 2355. In concluding that an “intermediated settlement” is an abstract idea, the Court noted that it was no more than a principle for doing business, and a “principle, in the abstract, is a fundamental truth; an original cause; a motive ... that cannot be patented.” *Id* (citations omitted). The Court found that the concept is “a fundamental economic practice long prevalent on our system of commerce.” *Id*. And, the “use of a third-party intermediary is also a building block of the modern economy.” *Id*.

Bilski likewise addressed whether the business method concept of “risk hedging” constituted an abstract idea. In that case, the Court came to a similar conclusion “that all of the claims at issue were abstract ideas in the understanding that risk hedging was a ‘fundamental economic practice.’” *Id* (quoting *Bilski*, at 611). Building blocks of the economy and fundamental economic practices fall within the category of abstract ideas because they lack a

concrete application and broadly pre-empt an entire field. “Abstract” in the context of these cases is consistent with common usage and dictionary definitions of the term: “thought [of] apart from concrete realities, specific objects, or actual instances,” “expressing a quality or characteristic apart from any specific object or instance, as justice, poverty, and speed,” and “theoretical, not applied or practical.” <http://dictionary.reference.com/browse/abstract> (last accessed 10/14/14).

Business methods in particular have received heightened scrutiny by the Supreme Court because of their non-technical and unscientific nature. Four Justices in *Alice* joined in a concurring opinion stating that business methods should never be patentable because they should not be considered “processes” under § 101. *Alice*, 134 S. Ct. at 2360. Since *Alice*, the Federal Circuit has observed that “[t]he claims at issue in *Alice* may well have described a useful and innovative method of doing business, but because they did not disclose any significant advance in science or technology, they fell outside section 101.” *I/P Engine, Inc. v. AOL Inc.*, 2014 WL 3973501 at * 5 (Fed. Cir. 2014). The Court also reasoned that “a process is nontechnological where its inventive concept is the application of principles drawn not from the natural sciences but from disciplines such as business, law, sociology, or psychology.” *Id.*

The ’985 patent claims are not an abstract idea akin to the broad business method claims in *Alice* and *Bilski*. The claims of the ’985 patent relate to advances in technological health science for a specific application in mobile medical treatment. Far from attempting to claim a “quality or characteristic apart from any specific object or actual instance,” the claims of the ’985 patent are tied to particular tangible methods, systems, and applications.

For example, it is easy to dispel the idea that the ’985 patent is directed to an abstract idea by reviewing claim 7 and its dependent claims:³

³ Each of the other claims are addressed below.

7. A computer readable medium having stored thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:

determining a current assessment of one or more diagnosed conditions in a patient based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;

updating an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;

reviewing the updated treatment plan for each of the diagnosed conditions;

determining if one or more changes are needed to the reviewed treatment plan for each of the diagnosed conditions;

changing the reviewed treatment plan if the one or more changes are determined to be needed;

providing the patient with the reviewed treatment for each of the diagnosed conditions; and

generating and providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.

8. The medium as set forth in claim 7 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.

9. The medium as set forth in claim 7 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.

Claim 7 is directed to a physical computer readable medium having particular instructions for a processor to track compliance with treatment guidelines by determining a “current assessment” of one or more “diagnosed conditions” in a patient “based on data about each of the diagnosed conditions” where the patient is at a “remote location” and on one or more “assessment guidelines,” and then “generating and providing compliance data” in relation to the

“updated treatment plan.” A reading of the claim terms reaffirms the wisdom in conducting claim construction prior to attempting to determine their scope in the context of determining whether they satisfy § 101.

Even without claim construction, a plain reading of the terms in the context of the claims and the specification manifests their concrete, tangible characteristics. For example, Claim 7 requires the medium to update the treatment plan, based on, among other things, “treatment guidelines.” “Treatment guidelines” are procedures that are not an abstract idea, but rather actually exist. *See, e.g.*, ’985 patent, 4:25-30; 55-60. One embodiment of the ’985 patent identifies NIH treatment guidelines, which are real, tangible, standards. By their nature, treatment guidelines cannot be so broadly read as to cover, say, a building block of medicine. *Id.*; *see* <http://www.aanma.org/advocacy/guidelines-for-the-diagnosis-and-management-of-asthma/> (showing an example of NIH treatment guidelines for asthma).⁴

“Compliance data” is tied to patient compliance or provider compliance in the context of a palpable treatment plan and assessment data processed in the computer readable medium. These are not abstract concepts or ethereal ideas. Instead, they represent physical data points, tied to each patient and treatment plan, and processed and updated according to particular instructions processed by a computer relative to finite treatment guidelines.

Even at this preliminary stage of the proceedings, and without the benefit of claim construction, it is clear that the claims do not pre-empt the entire field of “treating patients” or even “monitoring remote patients.” Motion at 12. There are limitations that if not present would allow for “treating and monitoring patients” but may not result in a finding of infringement, *e.g.*,

⁴ Whether the elements of the claims are old elements in a new combination or new is of no consequence to a §101 patentable subject matter analysis. *See Deihl*, 450 U.S. at 187. Should the issue of novelty or non-obviousness arise later in the case, Plaintiff will address those issues in due course.

the failure to employ the device at a location remote from the healthcare provider, the failure to provide compliance data, or the failure to employ assessment guidelines all within a computer readable medium. While not essential for “treating and monitoring remote patients,” the “compliance data” is undoubtedly an improvement because it allows for more accurate assessment and treatment. The Supreme Court noted analogous examples in *Diamond v. Diehr*, 450 U.S. 175, 188-89 (1981) in concluding that subject matter which provides an improvement in existing methods is patentable. *See also Alice*, 134 S. Ct. at 2358.

A review of these limitations shows that they are not a “principle, in the abstract, a fundamental truth; an original cause; a motive ... that cannot be patented.” *See Alice*, 134 S. Ct. at 2355. Nor is the apparatus of claim 7 (and as seen below in the remaining claims) some abstruse fundamental medical “practice long prevalent on our system.” *Id.* There is no risk here that the ’985 patent will “inhibit further discovery by improperly tying up the future use of the[] building blocks of human ingenuity.” To find that the ’985 patent claims an abstract idea would be to engage in an improper hunt for abstractions that ignore the concrete, palpable, tangible limitations of the invention. *Alice*, 134 S. Ct. at 2354.

For the foregoing reasons, the Court should find that the claims of the ’985 patent are not directed to abstract ideas, and are instead directed to tangible, patentable subject matter.

C. If the Court Finds that the ’985 Patent is Directed to an Abstract Idea, the Claims are Still Valid Under § 101 Because They Add Something Substantial.

If the Court agrees with LifeScan that the ’985 patent is directed to an abstract idea, the next task is to identify what the abstract idea is, and then determine under the “guideposts” provided in *Alice* and *Mayo* and related governing case law, and its application in this Court, whether the claims add something sufficiently substantial to meet the eligibility standard of §

101.⁵ *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2352-53 (2014); *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010) (identifying *Benson*, *Flook*, and *Diehr* as “guideposts”); *Diamond v. Diehr*, 450 U.S. 175, 188-89 (1981); *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Rockstar Consortium US LP v. Samsung Elecs. Co.*, No. 2:13-cv-00900 (E.D. Tex. May 15, 2014); *DDR Holdings, LLC v. Hotels.com, L.P.*, No. 2:06-cv-42-JRG, 954 F. Supp. 2d 509, 528 (E.D. Tex. 2013).

In particular, once the determination is made that the claims at issue are directed to an abstract idea, the next question is “what else is there in the claims” that may “transform the nature of the claim into a patent-eligible application[?].” *Alice*, 134 S. Ct. at 2355, 2357 (quoting *Mayo Collaborative Servs.*, 132 S. Ct. at 1297-98). In *Alice*, the Court described this next step as “a search for an inventive concept ... sufficient to ensure that the patent in practice amounts to significantly more” than the abstract concept itself. *Id.* at 2355. Each case is unique and depends upon the nature of the subject matter claimed. A comparison of this case with applicable case law readily demonstrates that the ’985 patent is claims eligible subject matter under § 101.

⁵ As an initial matter, properly framing the abstract idea is important in assessing whether something substantial is added to it. The more narrowly defined the so-called abstract concept is, the greater the burden is in showing that something substantial is added to it. LifeScan gives no justification for its statement that the “claims here cover an abstract idea for treating and monitoring a remote patient, nothing more.” Motion at 12. The abstract concept could as easily be defined as the title of the patent “monitoring and treating a patient,” or even “treating a patient.” Obviously, the latter more broadly worded concept provides greater latitude for the patent holder, because any definite addition to the concept will satisfy § 101. Nevertheless, My Health will focus the remainder of the brief on assuming that LifeScan’s articulation of the abstract concept is accepted. Even under this articulation, the claims are patentable as they add something substantial to the concept and create a “new and useful end.”

1. Supreme Court Precedent and this Court's Application of that Precedent Establish that the '985 Patent is Valid.

In *Diamond v. Diehr*, referenced throughout *Alice*, the disputed method claim fed inputs into a computer, which used a mathematical equation to run repeated calculations on the inputs until the results of the calculations indicated a completion state. *Alice*, 134 S. Ct. at 2358 (citing *Diamond v. Diehr*, 450 U.S. 175, 177-178 (1981)). The *Diehr* method claim was not entirely implemented on a computer, but included steps that required use of a computer as an “integral” part the invention. *Diehr*, 450 U.S. at 183. The *Diehr* Court held that “[i]n determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.” *Diehr*, 450 U.S. at 188-89. “The “novelty” of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.” *Id.*

On this front, *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067 (Fed. Cir. 2011) is misstated in LifeScan’s Motion. LifeScan states that the “Federal Circuit has warned that method *steps* ‘that simply collect and compare data, without applying the data in a step of the overall method, may fail to traverse the § 101 filter.’” Motion at 15, citing *Classen*, at 1067 (emphasis added). Whereas, the actual language from *Classen* does not mention method “steps” but rather the method as a whole: “*methods* that simply collect and compare data, without applying the data in a step of the overall method . . .” The subtle, but important, distinction of the precursor word “steps” makes it incorrectly appear that *Classen* applies to a single step of the ’985 patent, such as the “generating and providing . . .” step of claim 1. The Federal Circuit and Supreme Court, aware of the longstanding principle that steps must be

considered as a whole for eligibility analysis under § 101, did not warn against a data-collecting *step*. *Diehr*, 450 U.S. at 188 (1981). Rather, the Federal Circuit cautioned that a method directed only to data gathering, like the *one-step method* in *Classen*, could encounter eligibility obstacles. *Classen*, 659 F.3d at 1067. As set forth more fully below, *Classen*'s warning is inapplicable here because claim 1 of the '985 patent has at least six other tangible steps in addition to its allegedly suspect "generating and providing . . ." step.

The Supreme Court in *Diehr* observed that the claims in that case involved the use of a well-known mathematical equation known as the Arrhenius equation to cure tire rubber. *Id.* at 178. However, "they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Id.* at 187. The other steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." *Id.* The Supreme Court continued, "[o]bviously, one does not need a 'computer' to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of 'overcuring' or 'undercuring,' the process as a whole does not thereby become unpatentable subject matter." *Id.* The contribution to the curing process claimed by the patent in that case involved the process of measuring the actual temperature inside the mold; feeding the temperature measurements into a computer which calculated the cure time by use of the Arrhenius equation; and when the recalculated time equaled the elapsed time, the computer opened the press. *Id.* at 178-79.

The Court in *Diehr* stated that "[i]t is now commonplace that an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent

protection. *Id.* (citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923); *Cochrane v. Deener*, 94 U.S. 780 (1877); *O'Reilly v. Morse*, 15 How. 62 (1854); *Le Roy v. Tatham*, 14 How. 156 (1853)). The Court's rationale stemmed from finding a specific application that avoided broad pre-emption by limiting the claims to that particular purpose.

In contrast to *Diehr*, the Supreme Court in *Benson*, *Flook*, and *Alice* found that the disputed patents were not limited to a sphere of application, instead claiming a rote algorithm, a mathematical formula, and intermediated settlement that were all merely implemented on a computer. *Benson*, 409 U.S. at 71; *Flook*, 437 U.S. at 586; *Alice*, 134 S. Ct. at 2352-53. These claimed subject matter was found to be ineligible because claiming an inconsequential computer implementation of an otherwise standalone solution, with the computer "function[ing] solely as an obvious mechanism for permitting a solution to be achieved more quickly," did not add anything substantial to the abstract concepts. *Bancorp*, 687 F.3d at 1278-80 (quoting *SiRF*, 601 F.3d at 1333).

Two recent Eastern District of Texas cases, *Rockstar* and *DDR*, appropriately applied the framework set forth by the Supreme Court to uphold the validity of the patents at issue. *Rockstar Consortium US LP v. Samsung Elecs. Co.*, No. 2:13-cv-00900 (E.D. Tex. May 15, 2014); *DDR Holdings, LLC v. Hotels.com, L.P.*, 954 F. Supp. 2d 509, 528 (E.D. Tex. 2013). In *Rockstar*, this Court found that claim 5 of Patent No. 6,463,131, was directed to eligible subject matter.

The disputed claim in *Rockstar* read,

A method of notifying a user of an incoming communication event,
comprising:

determining a characteristic of the communication event;

selecting a notification based on the characteristic;

sending the user the selected notification;

receiving a selection from the user indicating a format for delivery of further notification information regarding the communication event; and

allowing the further notification information regarding the communication event to be sent to the user in the selected format.

Rockstar Consortium US LP, No. 2:13-cv-00900, at *2.

In line with the Supreme Court’s approach in *Alice*, this Court applied the *Mayo* two-step framework by first identifying the abstract idea and then determining the “inventive concept” that applied the abstract idea and brought the claim into the realm of subject matter eligibility. *Id.* at *6-8. This Court accepted the defendant’s identification of the abstract idea of “notifying the user.” *Id.* at 7-8. It then determined that claim 1 met the § 101 standard because it was “inherently limited to the sphere of application rather than abstraction” because (1) it included a “method of notification” that “requires [the] physical act [of] . . . delivery of some form of notification to a user;” (2) the “incoming communication event” limitation “clearly articulates a bounded universe of limitations;” and (3) the requirement of “particular input for a user relating to the format of further notifications, followed by the availability of the selected format” was a “two-way communicative process [] hardly inherent in the abstract idea of notification.” *Id.* at 8. This Court reasoned that having an application that includes the physical act of delivery, and requiring particular user input, establishes eligible subject matter.

In *DDR*, this Court found that where computer and networking equipment were integral to the claims, they were likewise valid: “interactions and linkages of computer machinery to generate composite web pages . . . are *integral* to each of DDR’s asserted claims.” *DDR Holdings, LLC*, 954 F. Supp. 2d at 528 (distinguishing *Bancorp*, 687 F.3d at 1279-80) (emphasis

added). This Court explained in *DDR* that *Bancorp*'s "'mathematical concept of managing a stable value protected life insurance policy' was an 'unpatentable . . . abstract idea because a mere mathematical comput[ation] was not dependent upon the computer components required to perform it.'" *Id.* at 528 ("In contrast, the interactions and linkages of computer machinery to generate composite web pages in this case are integral to each of *DDR*'s asserted claims.") (quoting *Bancorp*, 687 F.3d at 1279-80)). Unlike those that have been found to cover unpatentable subject matter, the claims of the '985 Patent do not seek to pre-empt an entire field. Instead, the claims of the '985 patent are limited to a specific application. This has long been held to constitute patentable subject matter. *E.g.*, *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

2. *The '985 Patent is Valid Under § 101 Because the Claimed Invention is Limited to a Sphere of Application, Adds Substantially to the Abstract Idea, and the Use of Computing and Networking Equipment is Integral.*

Claim 1 of the '985 patent satisfies *Mayo*'s second step of demonstrating an "inventive concept" by applying computing and networking equipment to a "new and useful end" of remote administration of medical treatment plans. The specific claimed application substantially adds to the bare abstract idea of monitoring a remote patient. Claims 1-3 of the '985 patent read:

1. A method for tracking compliance with treatment guidelines, the method comprising:

determining a current assessment of one or more diagnosed conditions in a patient based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;

updating an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;

reviewing the updated treatment plan for each of the diagnosed conditions;

determining if one or more changes are needed to the reviewed treatment plan for each of the diagnosed conditions;

changing the reviewed treatment plan if the one or more changes are determined to be needed;

providing the patient with the reviewed treatment plan for each of the diagnosed conditions; and

generating and providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.

2. The method as set forth in claim 1 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.

3. The method as set forth in claim 1 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.

The patent provides for remote health care administration through an improved way of gathering data remotely and updating a treatment plan in connection with a current assessment, treatment guidelines, and compliance data. As such, the '985 patent is propelled into the realm of eligibility consistent with the Supreme Court's "guidepost" precedents and this Court's authority.

Like the patent claims in *Diehr*, the '985 patent claims are improvements in existing technology. *See Alice*, 134 S. Ct. at 2358 (finding claims patentable if they improve an existing process). They are not directed to an abstract idea "simply implemented" on a computer. They claim a process that integrally employs computing equipment as a required element of the claimed invention. The computing and networking equipment is integral to claims 1-3 because several of the steps require transmitting data to and from a remote location. As with *Diehr*, the claims are not a trivial implementation of an otherwise standalone solution on a computer, but rather employ computing equipment as a required element of a claimed solution. This conclusion

is further supported by claims 7-9 (recited above), which specifically claim a computer readable medium, and claims 4-6 to be used in connection with a treatment processing system:

4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:

an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;

a treatment processing system that updates an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;

a review system that modifies the updated treatment plan if one or more changes are determined to be needed and provides a reviewed treatment plan;

a presentation system that provides the reviewed treatment plan for each of the diagnosed conditions; and

a compliance system that generates and provides compliance data based on the reviewed treatment plan and the updated treatment plans.

5. The system as set forth in claim 4 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.

6. The system as set forth in claim 4 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.

The claims are not an inconsequential computer implementation, but an application of computing and networking equipment as an essential, consequential part of a solution to facilitate remote administration of medical treatment plans. For example, claim 1 incorporates a computer processor as an “integral” part of the claimed invention” that ““play[s] a significant part in permitting the claimed method to be performed.”” *Bancorp*, 687 F.3d at 1278 (quoting *SiRF*, 601 F.3d at 1333). As in *DDR*, the ’985 patent claims require “interactions and linkages of

computer machinery” to implement several aspects of its invention, *e.g.*, the “providing the patient with the reviewed treatment plan.”

Moreover, the ’985 patent claims, like the claims in *Diehr*, do not purport to “pre-empt the entire field” of treating remote patients. Rather, only the treatment in “conjunction with all of the other steps in the[] claimed process,” is covered. The claims include multiple requirements that limit their scope to a specific application, such as “updating an existing treatment plan,” “reviewing the updated plan,” and “generating and providing compliance data.” These requirements distinguish the claims from those found in *Benson*, *Flook*, *Bilski*, and *Alice*.

Like the claims found valid in *Rockstar*, the ’985 patent claims contain limitations that are “hardly inherent in the [allegedly] abstract idea” of treating and monitoring a remote patient. Specifically, *Rockstar*’s “method of notification” that was in the sphere of a particular application because it required a “physical act of delivery of some notification to a user,” is analogous to the patent claims in this case which require “providing the patient with the reviewed treatment plan,” *i.e.*, a “physical act of delivery” of the reviewed treatment plan to a user. Just as *Rockstar*’s “incoming communication event” limitation “articulates a bounded universe of limitations” for the abstract process of “notifying a user,” the ’985 requirements of having an “existing treatment plan,” “updating [the] existing treatment plan” remotely, and “providing” an updated treatment plan to a patient, “bound the universe of limitations” for the allegedly abstract process of “treating and monitoring a remote patient.” These same ’985 limitations are “hardly inherent in the abstract idea” of treating and monitoring a remote patient. *Rockstar* is consistent with the Supreme Court’s subject matter eligibility “guidepost” jurisprudence, including *Alice*, and confirms that ’985 patent claims are directed to eligible subject matter.

The dependent claims add further limitations that are “hardly inherent” in treating and monitoring a remote patient and that further “bound the universe of limitations.” Dependent claim 2 limits “compliance data” in a manner that is specific and narrow: “wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.” Dependent claim 3 also limits “compliance data” in a manner that is “hardly inherent:” “wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.”

3. *The '985 Patent Does Not Merely Implement Mental Activities on a Computer.*

SmartGene, which LifeScan cites as exemplary patent-eligibility analysis in the field of “medical diagnosis and treatment,” is consistent with the Supreme Court holdings and Eastern District of Texas holdings cited above. *SmartGene, Inc. v. Advanced Biological Labs, SA*, 852 F.Supp.2d 42, 57 (DCC 2012). Like *Benson*, *Flook*, and *Alice*, in *SmartGene*, the computing device merely performed a mental process, which was insufficient to meet § 101. *SmartGene, Inc. v. Advanced Biological Labs, SA*, 555F. App’x 950 (Fed. Cir. 2014). However, ’985 patent claims do not merely incorporate a mental process in an inconsequential computer implementation. For example, claims 1-3 of the ’985 patent require transmission of data to a remote location, an act that simply cannot be accomplished by a human mind. *Id.* at 57.

Further, claim 7 is a computer readable medium to be used on a processor, where the computer is integral and required of the claim. Among other things, the treatment at a remote location requires the “physical act of delivery” of information, which requires tangible tools, including a computer processor and network. *See Rockstar Consortium US LP*, at * 7-9. The computer could not be stripped out of the claims without negating the apparatus. The claimed

apparatus is not directed to “mental processes” since it, *inter alia*, remotely monitors a patient, and could not be accomplished with “a pen and paper” as LifeScan suggests. *SmartGene* is further distinguished one of ordinary skill in the art would understand that claims 1-3 of the ’985 patent contain special programming code. *SmartGene, Inc.*, at 59 (absence of programming code weighs against eligibility). Consequently, *SmartGene, Inc.* along with *Benson*, *Flook*, and *Alice*, do not dictate that the ’985 patent is directed to ineligible subject matter.

4. *Rockstar is Still Good Law.*

LifeScan suggests that *Rockstar* is not good law because it “relies” on, among other cases, *Ultramercial*, a Federal Circuit subject matter eligibility case that the Supreme Court recently vacated and remanded for further proceedings in light of *Alice*. Although *Rockstar* did cite *Ultramercial* as one of several cases in its exposition of the law of subject matter eligibility, it did not explicitly rely on the facts of *Ultramercial*, or explicitly cite *Ultramercial* in its analysis of the facts. *Rockstar*, No. 2:3-cv-00900 at *7-9. Thus, *Rockstar*’s reference to *Ultramercial* undermines neither the precedential value of *Rockstar* nor the subject matter eligibility of the claims of the ’985 patent.

More significantly, *Ultramercial* was decided after, and in light of, the Supreme Court’s *Bilski* decision. LifeScan fails to articulate any reason why the *Ultramercial* principles cited in *Rockstar* will come out any differently in light of *Bilski* **and** *Alice* as opposed to under *Bilski* **before** *Alice*. *Alice* did not change *Bilski*. *Alice* and *Bilski* are consistent. *Alice* is a further application of *Bilski* and earlier subject matter eligibility jurisprudence to a set of facts similar to those in *Bilski*. *Alice*, 134 S. Ct. at 2356 (citing *Bilski* with approval). Moreover, this Court in *Rockstar* followed precisely the same two-step analysis set forth in *Mayo*, which was adopted in *Alice*. *Rockstar*, No. 2:3-cv-00900 at * 6-8; *e.g.* *Alice*, 134 S. Ct. 134 at 2355-2356. There is no

basis for LifeScan's implication that *Rockstar* is no longer good law, or that *Rockstar* would have been decided differently after *Alice*.

Finally, although *Ultramercial* has been vacated, LifeScan has not identified, and there does not seem to be, any tenable reason why *Ultramercial* will come out differently on remand. Even if *Rockstar* is, or becomes, suspect as a result of further *Ultramercial* proceedings in light of *Alice*, a diminution in *Rockstar*'s precedential value does not affect the '985 patent's subject matter eligibility. *Rockstar* is an application of higher court precedent. As established above, Supreme Court jurisprudence, including the plenary cases of *Benson*, *Flook*, *Alice*, *Bilski*, and *Diehr*, support a finding of subject matter eligibility.

5. *Novelty and Obviousness Analyses under § 102 and § 103 have No Bearing on § 101 Subject Matter Eligibility.*

Prior practice in the medical industry, whether actual or merely alleged, does not shape subject matter eligibility because it goes to novelty and obviousness, not whether an idea is abstract, or is a law of nature, or is a natural phenomenon. Otherwise, patent eligibility analysis would impermissibly collapse into an obviousness-type analysis under §§ 102 and 103.

The Northern District of California recently reinforced that novelty and obviousness analyses are misplaced in determining subject matter eligibility. In response to an accused infringer's argument that claim limitations, designed to limit an admittedly naturally occurring principle to specific applications, "were known and practiced in the art," the Northern District of California explained that it is impermissible to "conflate" patent subject matter eligibility with the questions of novelty and obviousness. *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, No. cv-12-01616 at *5-6 (N.D. Cal. March 7, 2014). The court relied on *Diehr*: "The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining

whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.” *Id.* (quoting *Diamond v. Diehr*, 450 U.S. 175, 188-89 (1981)).

Although many abstract ideas are “foundational” or “longstanding,” and are thus non-novel or obvious, these are not the particular characteristics of an idea that make it abstract. Consistent with this principle, the Supreme Court recently explained that the hedging at issue in *Bilski* was abstract not because “hedging is a longstanding commercial practice,” *i.e.*, not because it is non-novel or obvious, but because “it is a method of organizing human activity.” *Alice*, 134 S. Ct. 2347 at 2356 (2014).

LifeScan suggests that obviousness and lack of novelty furthers its case for invalidity under § 101. In addition to weaving this non-obviousness and lack of novelty notion into its argument as an underlying theme, LifeScan explicitly suggests that the claims are not directed to patentable subject matter because “they do not purport to require a novel or unique way of assessing a patient’s condition or revising a treatment plan.” Motion at 14, 15. Although Plaintiff reserves its arguments on claim construction, for purposes of this Opposition and a threshold finding of patentable subject matter under §101, Plaintiff does note that the ’985 patent discloses as preferred embodiments new and novel ways of assessing a patient’s condition from a remote location and updating the treatment plan based upon information obtained from the patient at a remote location. ’985 patent, 2:5-10. Moreover, Lifescan’s arguments are irrelevant to this Motion. As the Supreme Court explained, “[t]he ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.” *Diehr*, 450 U.S. at 189.

Indeed, all of the recent hoopla about patentable subject matter is unnecessary. *See id.* The categories of patentable subject matter in § 101 are very broad and were only intended by Congress to be a threshold inquiry. *Diehr*, 450 U.S. at 188; *see generally, Accenture*, 728 F.3d at 1347. Indeed, Congress’ intent in enacting § 101 is evident from “Committee Reports accompanying the 1952 Act which inform us that Congress intended statutory subject matter to “include anything under the sun that is made by man.” *Diehr*, 450 U.S. at 182 (*citing* S.Rep.No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952), U.S. Code Cong. & Admin. News 1952, pp. 2394, 2399).

Sections 102, 103, and 112 would prevent patent protection for truly abstract ideas or mental processes, without regard to an expansive reading of § 101 that does not follow the broad language of § 101. If patent protection was sought for a truly abstract idea like “gravity” or “justice,” even if those ideas were found to meet the threshold inquiry under § 101, it would be impracticable to enable these ideas under § 112. It is also impossible to believe that those ideas would not be shown to be invalid under sections 102 and 103.

Ultimately, in the present case, the claims of the ’985 patent are drawn to patentable subject matter under § 101 and case law interpreting that section. Sections 102 and 103 have no place in a § 101 inquiry and Defendant’s attempt to interject them should be rejected.

V. CONCLUSION

In light of the foregoing, Lifescan’s Motion should be denied and the ’985 patent should be deemed valid under § 101.

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Respectfully submitted,

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